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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 068351.0142

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on January 30, 2006

Signature _____

Typed or printed name Michael Wasaff

Application Number	Filed
10/625,998	07/24/2003

First Named Inventor: Mark B. Lyles

Art Unit	Examiner
1623	Patrick T. Lewis

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 46,861
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Michelle M. LeCointe
Typed or printed name

512.322.2580
Telephone number

January 30, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Mark B. Lyles
Serial No.:	10/625,998
Date Filed:	July 24, 2003
Group Art Unit:	1623
Examiner:	Lewis, Patrick T.
Title:	**NUCLEIC ACID ANTIOXIDANT COMPOSITIONS, METHODS FOR OBTAINING SUCH COMPOSITIONS AND FORMULATIONS THEREOF**

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Michael Wasaff

January 30, 2006
Date

Dear Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In response to the Final Office Action mailed November 1, 2005, Applicant respectfully submits the following and requests favorable review and action thereon.

PENDING CLAIMS

1. (Previously Presented) A method of preserving vitamins subject to oxidative damage comprising adding a sufficient amount of purified nucleic acid to the vitamins such that the rate of oxidative damage of the vitamins is reduced.

2. (Original) The method of Claim 1, wherein the nucleic acid comprises DNA.

3-9. (Canceled)

10. (Previously Presented) The method of Claim 1, wherein the vitamins comprise an aqueous solution of hydrophilic vitamins subject to oxidative damage.

11. (Previously Presented) The method of Claim 1, wherein the purified nucleic acid is added in a solvent with both hydrophilic and hydrophobic regions, and the vitamins are hydrophobic vitamins.

12. (Previously Presented) The method of Claim 1, wherein the nucleic acid is an aggregate of less than 50 μM in diameter, and the vitamins are hydrophobic vitamins.

13. (Previously Presented) The method of Claim 1, wherein the purified nucleic acid is sprayed onto the surface of the vitamins.

14. (Previously Presented) A reduced oxidative vitamin composition comprising:

a majority amount of a vitamin subject to oxidative damage; and

a sufficient amount of purified nucleic acid to reduce the rate of oxidative damage to the vitamin.

15. (Original) The composition method of Claim 14, wherein the nucleic acid comprises DNA.

16-24. (Canceled)

REMARKS

This Application has been carefully reviewed in light of the Final Office Action mailed November 1, 2005. At the time of the Final Office Action, Claims 1, 2 and 10-15 were pending in this Application. Claims 1, 2, and 10-15 were rejected. Applicant respectfully requests reconsideration and favorable action in this case.

Rejections under 35 U.S.C. § 112

Claims 14-15 were finally rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully disagrees and asserts Claims 14-15 fully comply with 35 U.S.C. §112, first paragraph. The specification is replete with disclosure describing vitamin compositions, *e.g.*, Example 1 describes a Vitamin C composition comprising 60 % to 80 % nucleic acid per 100 % of Vitamin C: "the optimal proportion of nucleic acid to Vitamin C by weight will fall between 60 % and 80 %." (Page 9, line 1 - page 10, line 1)

Rejections under 35 U.S.C. § 102

Claims 1, 2, 10 and 11 were finally rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 6,235,721 issued to Shibnath Ghosal ("Ghosal"). Applicant respectfully traversed and submitted the cited art does not teach all of the elements of the claimed embodiment of the invention. The Applicant asserted that a claim is anticipated only if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1997). Furthermore, the Applicant asserted that for a claim to be anticipated, "the identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully submitted previously and reasserts now that the art cited as anticipatory by the Examiner cannot anticipate the rejected Claims, because the cited art does not show all the elements of the present Claims.

The Applicant referred the Examiner to a Table in the cited art titled "Comparative Suppressive Effects of DNA Strand Scission." (*See* Col. 14, lines 24-41) The Applicant specifically informed the Examiner that the point of the Table is to show the effect of Vitamin C and blends of Vitamins C and E on DNA. Not the effect of DNA on Vitamin compositions. According to the Table (as previously pointed out to the Examiner), Vitamin C and a blend of Vitamins C and E have the unwanted effect of "DNA Strand Scission" which results in an unwanted linear form of DNA. (*See* Compositions 4 and 5 of the Table for "Linear Form of DNA" showing 30% and 60 % linear DNA.) As previously pointed out by the Applicant, it is clear to one of ordinary skill in the art that Table 1 of the cited art (Ghosal) is directed to a composition comprising a majority amount of DNA and a minor amount of Vitamin C and blends of Vitamins C and E. For example, in Table 1, Composition 1=DNA alone, Composition 2 = DNA + OH radical, Composition 3 = DNA + OH radical + Capros, Composition 4 = DNA + OH radical + #1 vitamin C/E blend, and Composition 5 = DNA + OH radical + vitamin C. And as noted previously, the DNA compositions containing vitamins contained an hydroxyl radical generated from $Cu(en)_2$ – hydrogen peroxide reaction which resulted in DNA strand scission. The cited art (Ghosal) certainly does not teach that DNA has the ability to reduce the oxidative rate of a Vitamin composition. In fact, based upon the cited art (Ghosal), one of ordinary skill in the art would not be inclined to combine DNA and Vitamin C or a blend of Vitamins C and E for any reason --much less for the reason of reducing oxidation in a Vitamin composition. Moreover, the cited art (Ghosal) at best only teaches the combination of CAPROS with absorbic acid. The pending claims are directed to "purified" amounts of nucleic acids, not DNA subjected to a $Cu(en)_2$ - hydrogen peroxide reaction. Consequently, it is respectfully submitted that the art relied upon by the Examiner, i.e., Ghosal, does not teach or even suggest a Vitamin composition comprising a sufficient amount of purified nucleic acids to reduce the oxidation rate of a Vitamin composition. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 12-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ghosal. In order to establish a *prima facie* case of obviousness, the references cited by the

Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). For the same reasons stated above in regards to anticipation, Ghosal alone fails to teach and/or suggest a reduced oxidative vitamin composition which includes in a majority amount of a vitamin and a sufficient amount of purified nucleic acids to reduce the oxidative rate of the vitamin composition. As pointed out previously to the Examiner, the cited art teaches that a minor amount of a vitamin results in DNA strand scission and neither teaches or suggests the addition of a minor amount of a nucleic acid to reduce the oxidative rate of a Vitamin composition. *Prima facie* obviousness has not been established and the rejection is improper. Favorable review is requested.

CONCLUSION

Applicant has now made an earnest effort to place this case in condition for examination. Applicant respectfully requests reconsideration of the application and allowance of the pending claims.

Applicant believes no fees are due, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-2148 of Baker Botts L.L.P. in order to effectuate this filing.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.322.2580.

Respectfully submitted,

BAKER BOTTS L.L.P.
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Date: 1/30/06

SEND CORRESPONDENCE TO:

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